REMARKS

Favorable reconsideration of this application, as presently amended and in light of the following discussion, is respectfully requested.

Claims 1-11, 13-19, and 21-38 are currently pending. Claims 1, 3, 22, and 24 have been amended by the present amendment. The changes to the claims are supported by the originally filed specification and do not add new matter.

In the outstanding Office Action, Claims 1-11, 13-19, and 21 were rejected under 35 U.S.C. §101 as being directed to nonstatutory subject matter because "the claims do not provide a sufficient tie to another statutory class..."'"; Claims 1, 6-9, 11, 13-17, 19, 21, 22, 27-30, 32-36, and 38 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,931,780 to Giger et al. (hereinafter "the '780 patent") in view of U.S. Patent No. 6,661,873 to Jabri et al. (hereinafter "the '873 patent"), further in view of U.S. Patent Application Publication No. 2004/0252873 to Avinash et al. (hereinafter "the '873 application"); and Claims 2-5, 10, 18, 21, 23-26, 31, and 37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the '780 patent, the '873 patent, and the '873 application, further in view of U.S. Patent No. 6,282,307 to Armato, III et al. (hereinafter "the '307 patent").

Applicants respectfully submit that the rejection of Claim 1 under 35 U.S.C. §101 is rendered moot by the present amendment to Claim 1. Claim 1 has been amended to recite the step of displaying a computer aided diagnostic symbol indicating a location of a region respecting the pathological change on at least one of the temporal subtraction image and the two images. Further, Claim 1 recites that the temporal subtraction image is an image of an anatomical region of a patient. The Federal Circuit's recent *en banc* decision in *In re Bilski* on October 30, 2008, requires that a method claim be either tied to a particular machine or apparatus, or transform an article or object to a different state or thing. Regarding the

transformation branch of the "machine-or-transformation" test, the Court stated that the transformation must be transformation of a physical article or <u>data</u> that represents a physical article. In this regard, the Court explained with respect to the *In re Abele* case, that the display of data that represents an X-ray tomographic image represents a transformation of data representing a physical object, since the X-ray data represents physical parts of the patient such as bones. In the present Claim 1, an image of an anatomical region of a patient is displayed, which is similar to the facts in the *In re Abele* case, which was viewed favorably by the *In re Bilski* court. Accordingly, Applicants respectfully submit that Claim 1 is directed to statutory subject matter under 35 U.S.C. §101 because it recites a transformation of data representing physical subject matter into a different state or thing. Accordingly, Applicants respectfully submit that amended Claim 1 (and all associated dependent claims) is directed to patent-eligible subject matter under 35 U.S.C. §101.

Similarly, Applicants note that Claim 14 is directed to a method that transforms a first bone image and a second bone image into a temporally subtracted image and outputs the temporal subtracted image. Applicants respectfully submit that Claim 14 (and all associated dependent claims) is directed to statutory subject matter because it recites a transformation of data that represents a physical article (i.e., a radiographic image of the bones of a patient). See *In re Bilski*'s discussion of the *In re Abele* case.

Further, Applicants note that the Office Action implies that the only manner in which a method claim can be directed to statutory subject matter under 35 U.S.C. §101 is if it is sufficiently tied to another statutory class. However, Applicants respectfully submit that this statement is incorrect in light of the "machine-or-transformation" test of *In re Bilski*.

Further, Applicants respectfully submit that computer-readable medium Claims 13 and 21 are directed to statutory subject matter under 35 U.S.C. §101 in view of the patent eligibility of Claims 1 and 14.

Amended Claim 1 is directed to a method, comprising: (1) obtaining a temporal subtraction image of an anatomical region of a patient from two images taken at respective times separated by a time interval that is long enough to allow for pathological change in the anatomical region; (2) extracting at least one feature from the subtraction image; (3) determining whether a region of interest in the subtraction image includes an abnormality associated with said pathological change, based on the extracted at least one feature, wherein the determining step comprising distinguishing a region of pathologic change from regions with a motion or misregistration artifact; and (4) displaying a computer-aided diagnostic symbol indicating a location of a region representing said pathologic change on at least one of the temporal subtraction image and the two images. Claim 1 has been amended to incorporate a limitation recited in dependent Claim 3. Accordingly, no new matter has been added.

Applicants respectfully submit that the rejection of Claim 1 is rendered moot by the present amendment to that claim. However, since Claim 1 has been amended to incorporate a limitation recited in Claim 3, Applicants will address the references cited in the rejection of Claim 3.

Regarding the rejection of Claim 1 under 35 U.S.C. §103(a), the Office Action asserts that the '780 and '873 patents disclose everything in Claim 1 with the exception of obtaining a temporal subtraction image from two images taken at respective times separated by a time interval that is long enough to allow for pathological change in the anatomical region, and relies on the '873 application to remedy those deficiencies. Further, regarding Claim 3, the Office Action appears to rely on the '307 patent to disclose additional limitations recited in Claim 3, but Applicants note that page 5 of the Office Action does not specifically address Claim 3 by name or the limitations recited in Claim 3. Accordingly, it is somewhat unclear

to Applicants what passages in the cited prior art are being relied upon to read on the limitations recited in original Claim 3.

The '780 patent is directed to a computerized method and system for radiographic analysis of bone structure. In particular, the '780 patent discloses a method that includes the steps of obtaining an image containing the bone, selecting a region of interest of the bone, determining at least one texture measure of the region of interest of the bone, and analyzing the bone using the at least one texture measure.

However, as admitted in the outstanding Office Action, the '780 patent does not disclose the use of multiple images at different times. In particular, Applicants respectfully submit that the '780 patent fails to disclose obtaining a temporal subtraction image of an anatomical region of a patient from two images taken at respective times separated by a time interval that is long enough to allow for pathological change in the anatomical region, as recited in amended Claim 1.

Further, Applicants respectfully submit that the '780 patent fails to disclose that the determining step includes <u>distinguishing a region of pathological change from regions with a motion or misregistration artifact</u>, as recited in amended Claim 1.

The '873 patent is directed to a method and system for decomposing soft tissue and bone images from low and high energy images acquired from an imaging system. In particular, the '873 patent discloses that artifacts may arise in the decomposed images due to anatomical movement between the two image acquisitions, for example, such as movement of a chest. In particular, the '873 patent discloses that the two images are acquired over a relatively short time period, "such as 100-200 ms." Further, the '873 patent discloses that, regarding the registration process shown in Figure 8, that "the process 400 is computationally

efficient because the motion artifacts are constrained to only a few pixels due to the relatively

short time interval between the low and high-energy image exposures."[1]

However, as admitted in the outstanding Office Action, the '873 patent fails to

disclose obtaining a temporal subtraction image of an anatomical region of a patient from two

images taken at respective times separated by a time interval that is long enough to allow for

a pathological change in the anatomical region, as recited in Claim 1. On the contrary, the

'873 patent discloses that the low and high-energy images are taken as close together as

possible such that the motion artifacts will be reduced due to movement of the patient.

Further, Applicants respectfully submit that the '873 patent fails to disclose that the

determining step includes distinguishing a region of pathological change from regions with a

motion or misregistration artifact, as recited in amended Claim 1.

The '873 application is directed to an image method that includes the steps of

generating a first derived member of a first data set, generating a first derived member of a

second data set, comparing a temporal change between the first derived member of the first

data set and the first derived member of the second data set, and generating a temporal

change image. In particular, the '873 application discloses that shift vectors are used and

shared among a plurality of registration modules, and that the images in the data set can

include one-dimensional, two-dimensional, three-dimensional, or other images obtained from

different modalities.

However, Applicants respectfully submit that the '873 application fails to teach or

suggest the step of distinguishing a region of pathological change from regions with a motion

or misregistration artifact, as required by amended Claim 1. Rather, the '873 application

merely discloses an image processing system having a temporal comparator to compare

various images in different data sets.

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[1] '873 patent, column 8, lines 26-30.

The '307 patent is directed to a method for identifying lung fields within a chest region based on posteranterior chest radiographic images, including the steps of generating first image data representative of a posteranterior chest image including the lung fields; performing global threshold analysis of the posteranterior chest image; constructing, based on the global threshold analysis, first initial lung segmentation contours; performing, based on the first initial lung segmentation contours, local threshold analysis to construct second initial lung segmentation contours; and applying a rolling ball filter to the second initial lung segmentation contours to smooth the shape of the second initial lung segmentation contours. Regarding the application of the '307 patent to the dependent claims, the Office Action states that the '307 patent discloses the use of grey level histogram analysis of images to construct binary images at different ranges of grey levels and an unsharp masking technique to identify and smooth a selected lung region.

However, the Office Action does not assert, and the '307 patent does not disclose the step of <u>distinguishing a region of pathological change from regions with a motion or misregistration artifact</u>, as required by amended Claim 1. Applicants respectfully submit that the '307 patent is not directed to determining misregistration artifacts or distinguishing them from regions of pathological change, as required by Claim 1.

Thus, no matter how the teachings of the '780 patent, the '873 patent, the '307 patent, and the '873 application are combined, the combination does not teach or suggest determining whether a region of interest in a subtraction image includes an abnormality associated with the pathological change, by <u>distinguishing a region of pathological change from regions with a motion or misregistration artifact</u>, based on the extracted at least one feature, as recited in amended Claim 1. Accordingly, Applicants respectfully submit that amended Claim 1 patentably defines over any proper combination of the cited references.

Independent Claim 22 is directed to an apparatus that includes various means that recite functional language similar to that recited in Claim 1. Applicants respectfully submit that any proper combination of the cited references fails to disclose means for distinguishing a region of pathological change from regions with a misregistration artifact, as recited in amended Claim 22. Accordingly, for the reasons stated above, Applicants respectfully submit that the rejection of Claim 22 is rendered moot.

Claim 14 is directed to a method, comprising: (1) obtaining a first dual-energy image, a first standard image, and one of a first bone image and a first soft tissue image from the first dual-energy image at a first point in time; (2) obtaining a second dual-energy image, a second standard image, and one of a second bone image and a second soft tissue image from the second dual-energy image at a second point in time; (3) using the first and second **standard** images to obtain shift vectors to obtain image registration; (4) performing temporal subtraction, using the shift vectors, <u>on one of the first and second bone images or one of the first and second soft tissue images</u> to produce a temporally subtracted image; and (5) outputting the temporally subtracted image.

Regarding the rejection of Claim 14 under 35 U.S.C. § 103(a), the Office Action asserts that the '780 patent discloses everything in Claim 14 with the exception of the acquisition of shift vectors, and relies on the '873 patent to remedy that deficiency. <u>The Office Action does not appear to rely upon the teachings of the '873 application in the rejection of Claim 14</u>.

As discussed above, the '780 patent is directed to a computerized method and system for radiographic analysis of bone structure. However, as admitted in the outstanding Office Action, the '780 patent fails to disclose using first and second <u>standard</u> images to obtain shift vectors, and performing temporal subtraction using the shift vectors, as recited in Claim 14.

As discussed above, the '873 patent is directed to a method of improving image clarity of soft tissue and bone images decomposable from first and second energy images acquired by a digital radiographic imaging system at different times. As noted by the outstanding Office Action, Figures 7 and 8 relate to the dual energy image acquisition system as well as the image registration process shown in step 316 and in Figure 8. However, as described with regard to Figure 8 "the process 400 registers the low and high-energy images 302 and 304 by obtaining shift vectors of one image with respect to the other."[2] Further, the '873 patent discloses that a warping transformation is then performed on the low-energy image 302 to align anatomy with respect to the high-energy image 304 prior to dual energy decomposition into soft tissue and bone images. Thus, the '873 patent discloses a registration process between the low and high-energy images prior to decomposition into soft tissue and bone images.

However, Applicants respectfully submit that the '873 patent fails to disclose using the first and second standard images to obtain shift vectors to obtain image registration, and perform a temporal subtraction using the shift vectors, on one of the first and second bone images or one of the first and second soft tissue images to produce a temporally subtracted image, as required by Claim 14. In this regard, Applicants note that Claim 14 recites a first dual energy image, a standard image and one of a first bone image and a first soft tissue image, as well as a second dual energy image, a second standard image, and one of a second bone image and a second soft tissue image obtained from the second dual energy image at a second time point. Further, Applicants note that Claim 14 requires the comparison of the first and second **standard** images to obtain shift vectors and then the application of those shift vectors to either the first and second **bone** images or the first and second **soft tissue** images to produce a subtracted image. On the contrary, the '873 patent merely discloses registration

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[2] '873 patent, column 8, lines 20-22.

between a <u>low and high-energy</u> image **prior** to producing the soft tissue or bone images.

Claim 14 requires obtaining shift vectors between first and second standard images, not high

and low-energy images. Moreover, the '873 patent is silent regarding obtaining shift vectors

from one set of images and applying the shift vectors to another set of images, as required by

Claim 14. Rather, the '873 patent discloses comparing two images for the purpose of

registration and applying the shift vectors obtained from that comparison to one of the two

images.

Applicants respectfully submit that the '873 application fails to remedy the

deficiencies of the '780 and '873 patents.

For the reasons stated above, Applicants respectfully submit that a *prima facie* case of

obviousness has not been established and that the rejection of Claim 14 (and all similarly

rejected dependent claims) should be withdrawn.

Independent Claim 33 is directed to an apparatus that includes means for using the

first and second standard images to obtain shift vectors, and means for performing temporal

subtraction, using the shift vectors. As discussed above, these functional limitations are not

disclosed by any proper combination of the '780 patent, the '873 patent, and the '873

application. Accordingly, for the reasons stated above, Applicants respectfully submit that a

prima facie case of obviousness has not been established and that the rejection of Claim 33

(and all similarly rejected dependent claims) should be withdrawn.

Regarding the rejection of dependent Claims 2-5, 10, 18, 21, 23-26, 31, and 37 under

35 U.S.C. § 103(a), Applicants respectfully submit that the '307 patent fails to remedy the

deficiencies of the '780 patent, the '873 patent, and the '873 application as discussed above.

Accordingly, Applicants respectfully submit that the rejections of Claims 2-5, 10, 18, 21, 23-

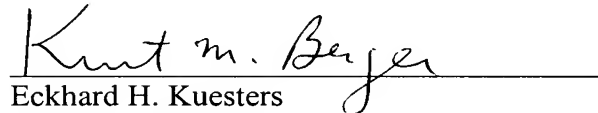26, 31 and 37 are rendered moot by the present amendment to Claims 1 and 22.

The present amendment also sets forth new dependent Claim 39 for examination on the merits. New Claim 39, which depends from Claim 1, clarifies the step of distinguishing the region of pathological change from regions with a misregistration artifact includes inputting the at least one feature into an automated classifier. New Claim 39 is supported by the originally filed specification and does not add new matter.[3]

Thus, it is respectfully submitted that independent Claims 1, 14, 22, and 33 (and all associated dependent claims) patentably define over any proper combination of the cited references.

Consequently, in view of the present amendment and in light of the above discussion, the outstanding grounds for rejection are believed to have been overcome. The application as amended herewith is believed to be in condition for formal allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Eckhard H. Kuesters
Attorney of Record
Registration No. 28,870

Kurt M. Berger, Ph.D.
Registration No. 51,461

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/07)
KMB/rac

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[3] See page 16 of the originally filed specification.

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